

EXHIBIT A



Abstract

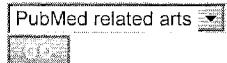
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The Barriers to Electronic Medical Record Systems and How to Overcome Them

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Institutions all want electronic medical record (EMR) systems. They want them to solve their record movement problems, to improve the quality and coherence of the care process, to automate guidelines and care pathways to assist clinical research, outcomes management, and process improvement. EMRs are very difficult to construct because the existing electronic data sources, e.g., laboratory systems, pharmacy systems, and physician dictation systems, reside on many isolated islands with differing structures, differing levels of granularity, and different code systems. To accelerate EMR deployment we need to focus on the interfaces instead of the EMR system. We have the interface solutions in the form of standards: IP, HL7 / ASTM, DICOM, LOINC, SNOMED, and others developed by the medical informatics community. We just have to embrace them. One remaining problem is the efficient capture of physician information in a coded form. Research is still needed to solve this last problem.

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As an intern at Boston City Hospital in 1965, I spent enormous amounts of time chasing and managing patient information—searching for the paper medical record, combing it for pertinent past history, calling diagnostic services for results, maintaining paper flowsheets, and writing daily progress notes while checking and crosschecking. Did the tests we ordered yesterday get done? Were the results received? Were any results abnormal? If so, how did they change compared with the previous results? Do any such changes have implications for current therapy? What is the current therapy? And on and on. This effort was largely bookkeeping work. Even in 1965, computers offered major assistance to financial bookkeepers. It seemed a relatively small stretch to imagine that they could do the same for clinical chart management. So when I finished my training in 1972, I threw myself into the tasks of building a computer-stored medical record at Wishard Memorial Hospital. I thought it would take about a year to solve the medical record problem. That year has stretched to a quarter century. Though we do have a very respectable medical record system,¹ we are still working to complete it.

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The medical record system at Wishard and the Indiana University Medical Center now carries

records for more than 1.4 million patients, including more than 6 million prescription records, hundreds of thousands of full text narrative documents, nearly 200,000 EKG tracings, millions of orders per year, and 100 million coded patient observations and test results. It includes all diagnoses, all orders, all encounters, all dictated notes, and a mix of clinical variables from selected clinical sites. It does carry a great proportion of what care providers need to know about the patient, but it does not include everything. Physicians still handwrite daily notes in the hospital and most visit notes in clinics, and we don't capture most of that content in the computer. So, we still have a paper chart, but our Electronic Medical Record (EMR) has eliminated most of the need to access it. Physicians always turn to the computer record first—either through direct terminal look-up (Fig. 1) or through their paper pocket rounds report (Fig. 2), so called because, when folded in half, it fits perfectly into the white-coat pockets where physicians carry them (Fig. 3).



Figure 1

Web browser display of RMRS patient data showing EKG measurement and diagnoses as well as links to the full tracing which can be viewed by clicking on the icons at the bottom of the figure.



Figure 2

Pocket rounds reports contain problems, action, allergies, orders, lab tests, vital signs, and weight in flow sheet format with brief impression of imaging studies.



Figure 3

Physician carrying pocket rounds in typical configuration.



Figure 4

Radio-linked portable computers on a rolling IV pole stand used for gathering nursing assessments on a regular basis, and physician's notes on an experimental basis.

A number of other institutions have successfully installed and maintained medical records, many beginning in the 70s.^{2,3,4,5,6,7,8,9} These early adopters have demonstrated the many values of EMRs. They have demonstrated through clinical trials that reminders generated by EMRs have substantial and beneficial effects on physician behavior and care processes.^{10,11,12,13,14} They have demonstrated the advantages of computer-organized (but printed) information,^{15,16} and their providers are enthusiastic about the ready availability of patient information that an EMR can provide. The EMR does eliminate the logistic problems of the traditional medical record even when it does not

completely replace the paper chart.

I hear people ask how we can motivate institutions to build electronic medical record systems. From what I can tell in my visits to care institutions, everyone already wants them. They want them to solve the logistic problems of the paper chart; can't find the record, can't find the particular items of information that are within it,¹⁷ can't read it. Multi-site organizations are desperate for the EMR because there is no way to move a single paper chart to the multiple sites that require it. They want the EMR to improve the quality and coherence of the care process through automated guidelines and care pathways. They want them to provide aggregate data about patients by disease, by procedure, by doctor, and other levels of aggregation for clinical research, outcomes management, process improvement, and the development of new care products. They want them to save money in paper storage, filing costs, time spent searching for the physical record, and regulatory reporting.

If “everyone” wants EMRs, and the sources of electronic patient data are so abundant, why are they so scarce? The answer is twofold. First, the sources of electronic patient information that do exist (e.g., laboratory data, pharmacy data, and physician dictation) reside on many isolated islands that have been very difficult to bridge; and second, we have not quite figured out how to capture the data from the physician in a structured and computer understandable form. Figure 5 illustrates the problem of the many islands of data. As the patient encounters the health care providers, he or she leaves a trail of medical information at many sites: the private physician's office, the hospital, then a nursing home, then a home health care system, each of which uses a different primary computer system, a different laboratory, and (probably) a different pharmacy and radiology service. Each carries a portion of that patient's medical information. The patient may visit many different physicians' offices and/or use many pharmacies. Even within a single organization such as a hospital, many separate islands of information exist. Table 1 lists the separate systems we have counted in two Indianapolis hospitals, and this does not count all of the separate systems related to administration, accounting, payroll, paging, and telephone.



Figure 5

Illustration of the islands of data created as a patient traverses the care system.



Table 1

Too Many Different Separate Systems with Different Data Structures

Each island system contains different data, different structures, and differing levels of granularity, and each uses a different code system to identify similar clinical concepts. The external islands differ even more than those within an institution. They each tend to use different patient, provider and location identifiers, and the numbers of such independent systems are legion (Table 2). These many different and cubbyholed systems present an enormous entropy barrier to the joining of patient data from many source systems in a single EMR. The work required to overcome this entropy by interfacing to the many different islands and regularizing the data they contain has been more than most can afford.

Table 2

The Number of Different Kinds of Care Providing Sites in the United States



Further, even large organizations such as hospitals do not capture all of the information of interest to their practitioners. They send some of their laboratory tests to external reference laboratories. Patients typically fill their discharge prescriptions at their community pharmacy, not the hospital's pharmacy. Institutions are invariably frustrated when they realize during the planning phase that they will not be able to achieve all of their quality assurance goals—for example, the identification of patients who need influenza vaccines—without additional investment in manual data collection because they do not have information about influenza shots given in nursing homes and the physicians' offices.

So, what are the solutions? For many of the last 30 years, we in the medical informatics community have fixated on the medical record system—the vessel that carries the patient data—and how to build one. We have been focusing on the wrong part of the problem. Medical data does not generate spontaneously within the medical record. It all comes from sources elsewhere in the world, and all of the obstacles and most of the work of creating an EMR relate to these external data sources and the transfer of their data into the EMR. The vase/face illusion is a metaphor for the problem (Fig. 6). We have been looking at the vase, when we should have been looking at the faces.



Figure 6
Vase/faces illusion.³² A question of focus.

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The solution to the first problem, that of merging data from many sources into one EMR, lies in standards which the informatics community began to develop in the mid 80s.¹⁸ Standards provide the bridges to the many islands of electronic patient data so that the data can inexpensively be combined into an electronic medical record.

The standards needed to transport patient data from one system to another inexpensively are in place. With these standards we can solve many of the problems and create a first-stage medical record system from the extensive medical data that already exist in systems such as laboratory, pharmacy, dictation, scheduling, EKG cart, and case abstract systems.

Standard mechanisms for communicating over networks in a secure fashion exist, as do standards for delivering structured medical record content like patient registry records, orders, test results, and standard identifiers for coding many (but not yet all) of the concepts we want to report in the fields of such structured records.

The communication standards of choice are the internet standards including the base internet protocol for sending packets of information, the Secure Sockets Layer for encrypting transmitted information, Certificates for verifying the identity of the communicant, and EDI over the Internet for secure MIME e-mail, to name just a few. The Internet protocols are the communications standards of choice for a private *Intranet* as well as for the public *Internet*. I believe that available or announced security tools are more than adequate for the threat over the public Internet. Those who do not believe can limit or avoid access to the public Internet until they can reach the necessary level of confidence. Anyone who would like to explore these Internet standards can download them from the Internet at no cost. (See <http://www.internic.net/std/std-index.txt> for formal standards, and

<http://www.ietf.org/lid-abstracts.html>(for draft standards.)

HL7¹⁹ is the message standard of choice for communicating clinical information such as diagnostic results, notes, referrals, scheduling information, nursing notes, problems, clinical trials data, master file records, and more. It is used by more than 2,000 hospitals, by the US Centers for Disease Control and Prevention (CDC) for immunization, communicable disease and emergency visit information, as well as by most large referral laboratories. It is also widely used in Canada, Australia, New Zealand, Japan, and in many countries in Europe. Its nearly 2,000 members include 90% of the health system vendors, as well as major pharmaceutical and computer manufacturers. HL7/ASTM provides the structure (like a set of database records) for interchanging patient information between source systems like laboratory, dictation and pharmacy systems data repositories such as cancer registries, performance databases and medical record systems. HL7 provides all of its minutes, proposals and its draft standards on the internet at no cost. (See <http://www.mcis.duke.edu/standards/HL7/h17.htm>.)

DICOM²⁰ is the standard of choice for transmitting diagnostic images. It is supported by all imaging vendors, and is working closely with HL7. Information about the DICOM standard can be obtained from http://www.xray.hmc.psu.edu/dicom/dicom_home.html.

The message standards do not specify the choice of codes for many fields. They do provide a mechanism for identifying the code system for every transmitted code. This pluralistic strategy was the only alternative in the past because universal code systems did not exist for important topics such as laboratory tests and clinical measurements; so institutions used their own local codes. Fortunately, universal code systems are now available for subject matter such as units of measure (ISO+²¹), laboratory observations (LOINC²²), common clinical measurements (LOINC), drug entities (NDC²³), device classifications (UMDNS²⁴), organism names, topology, symptoms and pathology (SNOMED,²⁵ IUPAC²⁶), and outcomes variables (HOI²⁷). Even better, most are available without cost. So, for at least some source systems, we have all of the pieces needed for creating EMRs inexpensively from multiple independent sources, inside and outside of a health care organization.

I mention LOINC because it fills in an important gap (and it has occupied much of my recent life). At least four large commercial laboratory vendors (Corning MetPath, LabCorp, ARUP, and Life Chem) representing more than 20% of the nation's laboratory testing, and other care institutions (Intermountain Health Care, Indiana University Hospitals, University of Colorado, and the Veterans Hospitals) are actively converting to the LOINC laboratory test code standards mentioned above. The Province of Ontario, Canada, is using LOINC for a province-wide system, NLM incorporated it into the UMLS,²⁸ and ICD10-PCS has also incorporated it.

Readers should lobby their organizations, information system vendors, and external diagnostic study suppliers to use these communication, messaging and code systems standards. Information about all of them can be obtained from the following web site.

<http://www.mcis.duke.edu/standards/guide.htm>

The sooner everyone adopts them, the faster and easier it will be to build first-stage EMRs.

The problem of linking to sources outside of one's organization is a little more difficult because of the differences in patient, provider, and place of service identifiers from institution to institution. However, these problems can be overcome in a local institutional cooperative by using linking algorithms with nearness metrics for identifiers such as patient name,²⁹ and by making local choices of standards (e.g., state license number for provider identifier). P.L. 104-191 (formerly the Kassebaum-Kennedy bill) requires a national patient and provider identifier, so it is likely that such identifiers will be available in the United States soon.

The data from large ancillary services (e.g., laboratory and pharmacy) and dictated notes (discharge, visit notes, diagnostic reports) make a very good starting EMR. First-stage EMRs can also provide reminders and retrievals to support a quality-assurance mechanism, and they can provide some management and research capability. However, these benefits are all constrained by the scope of the data available within the EMR. For example, a hospital would rarely have full information about pediatric immunization records, so it could not generate accurate reminders or quality assurance reports about pediatric immunizations without additional investment in interview and data entry time to capture and enter this information.

The benefits are also constrained by the degree to which information is stored as free text rather than as structured and coded results. For example, if blood pressures levels are buried in the free-text narrative of a visit note, the computer will not be able to find and interpret them for reminders or quality-assurance activity. Those planning the creation of an EMR should take the time to inventory their planned data sources against the data needs of particular management, or reminder projects, to see if the EMR will be able to perform those particular functions, and if not, consider investing in manual data collection to achieve their important goals.

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The starred ancillary systems (Table 1) have been tamed and domesticated through many generations of development. Laboratory test results, for example, are stored in databases, with specific fields dedicated to each atom of information: e.g., one field for the test ID, one for the test results, other fields for the normal ranges, units, and responsible observer. Most of these fields contain codes or numbers that can be “understood” and processed by the computer. The ultimate EMR promises to capture whatever patient data is needed to perform any EMR task, such as outcomes analysis, utilization review, profiling, costing, etc. These promises excite CEOs at hospitals and managed care organizations. However, much of the data required by the advanced functions of an EMR comes from physicians (e.g., particular clinical findings and disease severity), and this information has yet to be tamed and domesticated. Physicians usually just record their observations as a glob of free text. So these promises may be difficult to keep.

There are two major problems related to information collected by physicians. First, there is the problem of translating free-text notes into computer understandable codes and structure. In many settings, physician notes *are* stored in computers via dictation and transcription, and we can assume that all notes will eventually be via computer voice understanding. But, how will we convert this text information into computer understandable meaning? How can we code it? Secondary human coding is error prone and expensive even at the current level of granularity which is too coarse for many of the sophisticated EMR functions. Despite decades of investment, computers cannot accurately interpret unconstrained text, though some promising work continues.³⁰ So we are left the option of the physician coding his / her own data as they enter it through selection menus and other techniques.

Entering structured data requires more user time than entry of free-text information. It requires the user to map the concepts into the computer's concepts and to spend time searching for the “right” computer code or phrasing. The computer often asks for more specific items of information or for a more granular representation than the user knows.

The second problem is that much of the data that managers and outcomes analysts would like to have (e.g., formal function status and detailed guideline criteria) are not provided in any form (narrative or coded) in the current physicians notes.³¹ Further, we do not know exactly how much information is really needed. For some disorders, such as angiography and knee replacement surgery, data sets have been developed, but we do not know the operating characteristics or predictive value of the data elements within these data sets. For most subject areas we have not even proposed, let alone tested and refined, a data set.

How do we define and collect the soft data elements that are described in providers' notes? Do we define each variable as a formal survey question? If so, each different way of stating the question and each different set of response answers defines a distinct variable. We have validated survey instruments for some subject matter (e.g., alcoholism, CAGE, Depression-Hamilton, general health status SF36 SF12), but we lack them for many subjects and for much of specialized clinical care. Another problem is that checklist symptom questionnaires elicit many more (and less important) symptoms than open-entry questions, and it is difficult to know how to interpret this difference. We have differences between patient-completed and provider-completed (and filtered) questionnaires.

The above observations and our experience with order entry convinces me that full coding of all medical record content will not be possible for the foreseeable future. This means we will have to live with a mixture of coded and free-text information. The challenge is to find where to draw the line. What categories of information are valuable enough to justify coding, and what can be left as free text? What level of granularity is required? Do we really want to code the presence of an S4 gallop if we are likely to have a cardiac echo and all of its fully coded hemodynamic measurements for patients with heart symptoms? These are questions that could be answered empirically but require considerable work.

Whatever we come up with, the line is likely to be drawn fairly conservatively because the productivity demands limit the amount of physician time that could be dedicated to structured data entry. We might expect a more complete set of patient social and functional status measures at the first visit, perhaps collected via a direct patient survey instrument, a handful of structured questions per major diagnosis, a larger but still modest set of questions for each procedure and hospitalization, and—my own favorite—a coded impression on every imaging study report. If office practitioners can muster the effort to code their diagnostic impression, why shouldn't an imaging service do the same?

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To get quickly to the first-stage EMR we need to adopt as widely as possible the existing informatics standards. This will enable the appropriate connections of systems to provide hospitals and office EMRs with the data that the care providers at those sites need to give the best medical care. For the ultimate medical records we have to solve two grand challenges: the efficient capture of physician gathered information—some of it in a computer-understandable format—and the identification of a minimum but affordable set of variables needed to assess quality and outcomes of care.

Notes

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